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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,015

09/26/2005

Peter Forsell

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23117 7590 12/23/2009
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EXAMINER

GILBERT, SAMUEL G

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

12/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,015	Applicant(s) FORSELL, PETER	
	Examiner Samuel G. Gilbert	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) 15-34 and 36-114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-14 and 35 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/1/2005 and 8/19/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and the species of figures 1-3, claims 1-14 and 35 in the reply filed on 10/26/2009 is acknowledged. The traversal is on the ground(s) that the figures identified by the examiner are not different species because such figures do not show all the same elements much less alternative embodiments of all the same elements. This is not found persuasive because the examiner believes the figures show different embodiments of an implantable system including an implantable pump.

The requirement is still deemed proper and is therefore made FINAL.

The applicant also argues that claim 15 is not generic and upon reconsideration the examiner agrees.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulte (4,190,040).

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Claim 1 - the examiner is taking element -3- to be an implantable pump, elements -8- - -10- and -12- - -14- teach a wall forming a chamber, first wall portion includes elements -12- - -14- and a second wall portion -8- - -10- which is displaceable relative to the first wall to pump fluid into implant -1-. The second wall portion -8- - -10- is self sealing, column 2 lines 23-37. Element -5- is a penetrating needle.

Claim 2 - the membrane is inherently manually displaceable.

Claim 3 - figure 3 shows the membrane in a first position having a first volume and when depressed the membrane would press to the first wall portion and the chamber would have a smaller volume.

Claim 4 - the membrane is flexible and takes the shape of a semi-sphere (dome), column 2 lines 34.

Claim 8 - the chamber is substantially emptied when the membrane is in the second position.

Claim 9 - the membrane includes a first layer -9- and a second layer -8-. The first layer having better strength properties and the second layer having better sealing properties.

Claim 10 the first layer(silicone rubber) is harder than the second layer(silicone gel).

Claim 11 - the second layer is between the first layer and the chamber.

Claim 12 - element -10- is a third layer harder than the second layer.

Claim 13 - the silicone gel layer inherently has a Shore hardness of less than 20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 14 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen et al (5,562,598, hereinafter Whalen) in view of Schulte (4,190,040).

Whalen teaches an artificial sphincter having an infusion port and separate magnetically operated pump. The pump is activated by placing an external magnet close to the pump. The internal magnet drives the pump membrane and locks it in place until an external magnet is removed.

Schulte teaches a pump that also functions as an infusion port but does not teach locking means.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the magnetic drive/locking means taught by Whalen with the pump/port of Schulte to produce a port/pump with a magnetic drive/locking mechanism as taught by Whalen. Further, the combined pump/port then would replace the separate pump and port taught by Whalen to form an implantable sphincter with an implantable magnetically driven/locked pump/port. Such an arrangement would produce the benefit of requiring a single implantable element in place of two separate

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elements pump -30- and port -160-. This arrangement would reduce the possibilities of complications by shortening surgery time and reducing the number of implanted objects.

Claim 6 - the membrane is "pushed" by magnetic forces and locked in the second position.

Claim 14 - use of the device of the combination would produce a pump/port used in an incontinence device.

Allowable Subject Matter

Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or fairly suggest an implantable pump as claimed including a locking device which is released upon pushing the membrane and the membrane resumes its first position.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 4,342,308, 5,435,230 and Patent application 2003/0073880 teach related pumping devices and implantable devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel G. Gilbert/
Primary Examiner, Art Unit 3735